

REMARKS

Claims 1 to 40 and 42 to 55 appear in this application for the Examiner's review and consideration. Claims 1 to 32, 39, 40, and 46 to 53 have been withdrawn from consideration, as being drawn to non-elected subject matter. Claims 33-38, 42-45, 54, and 55 are currently rejected. Claims 33-35 and 38 have been cancelled, claims 36 and 37 have been amended to change the dependency of these claims. Claims 42 and 43 have been amended to more clearly define the claimed subject matter. Claim 45 has been amended to no longer depend from claim 44 whereas claim 44 has been amended to depend from claim 45. Submitted herewith is a further declaration under 37 CFR 1.132 by Claude Singer for the Examiner's review providing further evidence that lansoprazole prepared according to the methods recited in the references of record does not meet the purity and stability limitations of the claimed invention. Reconsideration and allowance of the claims is respectfully requested in view of the following remarks.

1. Claims 33-38, 42-45, 54, and 55 were rejected under 35 U.S.C. 112, second paragraph for being indefinite.

Claims 33 to 38, 42 to 45, 54, and 55 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for the reasons set forth on pages 2-3 of the Office Action.

According to the Examiner, claims 33-35 are improper product-by-process claims, as such claims are improper in the same application where it has been demonstrated that the compound in question may be described by means of a chemical structure. Although applicants disagree with the Examiner on this point, claims 33-35 have been cancelled in advance prosecution of the currently pending application. Accordingly, the rejection under 35 U.S.C. §112, second paragraph, of claim 33-35 is now moot and withdrawal of the rejection is respectfully requested.

With regard to the recitation of the term "containing" in claims 42 and 43, the Examiner asserts that such open-ended term allows for the inclusion of other parameters not contemplated by Applicants and which according to the Examiner is not allowed in compound claims. In response, Applicants submit that removing all impurities is practically impossible and therefore compounds invariably include some impurities. The recitation in the currently pending claims of "containing less than" identifies an impurity in the lansoprazole that is present in less than a certain amount upon storage over time, thereby

identifying the lansoprazole as a stable lansoprazole. In lansoprazole that is not stable the recited impurities contained in the compound are present in significantly higher amounts upon storage. Thus the recitation in claims 42 and 43 of “containing less than” more clearly describes the stable lansoprazole of the claimed invention as opposed to non-stable lansoprazole. Applicants therefore disagree with the contention of the Examiner that such term as “containing” may not be used when a compound is claimed. However, in order to advance prosecution of the currently pending application Applicants have amended the claims to recite “having less than” instead. Applicants submit that the claimed clearly describe the claimed invention. Therefore withdrawal of the rejection under 35 U.S.C. §112, second paragraph, of claims 42 and 43 is respectfully requested.

With respect to the alleged lack of antecedent basis for the recited limitations in claim 45, the Examiner asserts that there is no basis for the term “six months” in claim 45. Although Applicants disagree with the Examiner’s assertion of a lack of antecedent basis, claims 44 and 45 have been amended in order to advance prosecution of these claims. As amended claim 45 no longer depends from claim 44, and claim 44 is no longer an independent claim but depends from claim 45. Therefore, applicants submit that sufficient antecedent basis is provided. Accordingly, claims 44 and 45 clearly define the claimed subject matter and withdrawal of the rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Therefore, the claims particularly point out and distinctly claim the subject matter Applicants regard as the invention. Accordingly, it is respectfully requested that the Examiner withdraw the rejections of claims 33 to 38, 42 to 45, 54, and 55 under 35 U.S.C. §112, second paragraph.

2. Claims 33-38, 42-45, 54, and 55 were provisionally rejected under the judicially created doctrine of obviousness type double patenting.

Claims 33-38, 42-45, 54, and 55 are provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-7 and 29-38 of copending U.S. Application Ser No. 10/717,325 in view of Haleblian et al., Chemical & Engineering News, US Pharmacopeia, Muzaffar et al, Jain et al, Taday et al, Concise Encyclopedia Chemistry and Brittain et al. (Polymorphism in Pharmaceutical Solids, pages 1-2, 185). According to the Examiner the stable compound and compositions are disclosed in this copending application. In response, Applicants wish to defer filing a terminal disclaimer

until the currently pending claims are deemed allowable, at which time, Applicants intend to file a terminal disclaimer.

Applicants thus submit that the entire application is now in condition for allowance, an early notice of which would be appreciated. Should the Examiner not agree with Applicants' position, a personal or telephonic interview is respectfully requested to discuss any remaining issues prior to the issuance of a further Office Action, and to expedite the allowance of the application.

Respectfully submitted,
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